DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1065d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

March 29, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 43

Peter Jacobson
Chief Executive Officer
St. Joseph's Area Health Services
600 Pleasant Avenue
Park Rapids, Minnesota 56470

Dear Mr. Jacobson:

On March 8, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certificate #182659). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 non-compliance was documented:

Level 1 Non-Compliance

1. The system to communicate results is not adequate. The system in place does not provide timely lay summaries to all patients. Written lay summaries are required for mammography assessment category designations.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. The problem was identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition represents a serious violation of the law, FDA may take regulatory action without further notice to you. This action includes, but is not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was documented on the inspection report provided to your site at the close of the inspection:

Level 2 Non-Compliance

2. Failure to document corrective action(s) before conducting further clinical exams for a failing phantom image score, or a phantom background optical density, or density difference outside the allowable regulatory limits. Mammography system = [redacted] Model = DMR; Room = Mammography; ACR unit designation = 1.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations:
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Cheryl A. Bigham
Acting Director
Minneapolis District

TWG/ccl

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